

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004G-0381]

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Certifier R. LEDESMA

Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." The draft guidance is intended to clarify the circumstances under which FDA may access and copy records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2003 (Bioterrorism Act) and establishes procedures to exercise its authority.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 45 days after date of publication in the Federal Register]*, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" to Rudaina Alrefai (see **FOR FURTHER INFORMATION CONTACT**). Send cf0463

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one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Rudaina Alrefai, Division of Compliance Information and Quality Assurance (HFC-240), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6815, e-mail: rudaina.alrefai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” The Bioterrorism Act created a new section 414 (21 U.S.C. 350c) entitled “Maintenance and Inspection of Records,” in the Federal Food, Drug, and Cosmetic Act. Under this new authority, the Secretary of Health and Human Services (the Secretary) may by regulation establish requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records. In addition, sections 414(a) and 704(a) (21 U.S.C. 374(a)) authorize FDA to access and copy all records related to an article of food if the following occurs: (1) The Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to

humans or animals, and (2) the records are necessary to assist FDA in making such a determination.

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule entitled “Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,” in which the agency is establishing requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records.

The purpose of this draft guidance is to describe the procedure that FDA intends to follow to exercise its new authority, and clarify the circumstances under which FDA may access and copy records under the Bioterrorism Act.

The agency has adopted good guidance practices (GGPs) that set forth the agency’s policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is being issued as a level 1 guidance consistent with GGPs. The draft guidance represents the agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.

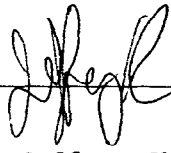
Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the draft guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.cfsan.fda.gov/guidance.html>.

Dated: 11/24/04
November 24, 2004.

JS
12-2-04



Jeffrey Shuren,
Assistant Commissioner for Policy.

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